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No. 88-20

In the Supreme Court of the United States

OCTOBER TERM, 1988

JAMES A. BRADSHAW, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether Section 303(b) of the Food, Drug, and Cosmetic Act, 21 U.S.C. 333(b), makes it a crime to introduce misbranded drugs into interstate commerce, in violation of Section 301(a) of that Act, 21 U.S.C. 331(a), with the intent to defraud or mislead the Food and Drug Administration or a state regulatory agency.

2. Whether the indictment in this case was sufficient to inform petitioner of the charges against him.

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OPINION BELOW

The opinion of the court of appeals (Pet. App. 1a-16a) is reported at 840 F.2d 871.

JURISDICTION

The judgment of the court of appeals was entered on March 25, 1988. On May 25, 1988, Justice Kennedy extended the time within which to file a petition for a writ of certiorari to and including June 23, 1988. The petition for a writ of certiorari was filed on June 22, 1988. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Section 301(a) of the Federal Food, Drug, and Cosmetic Act (FDCA or Act), 21 U.S.C. 331(a), prohibits, inter alia, the introduction into interstate commerce of any misbranded drug. Under Section 503(b)(1) of the Act, 21 U.S.C. 353(b)(1), a drug is misbranded if it is a prescription drug that is dispensed without a prescription.[1] Section 303(a) of the FDCA, 21 U.S.C. 333(a), makes it a misdemeanor to commit one of the prohibited acts set forth in Section 301(a), 21 U.S.C. 331(a). If Section 301 is violated "with the intent to defraud or mislead," then under Section 303(b) of the FDCA, 21 U.S.C. 333(b), the offense is a felony.[2]

2. The evidence at trial is summarized by the court of appeals. Pet. App. 4a-6a. It showed that petitioner distributed anabolic steroids, androgenic hormones, and other drugs used by athletes to "increase muscle mass and thereby improve athletic performance." *Id.* at 4a. Because of the "many harmful side effects" of those drugs, the Food and Drug Administration (FDA) has not approved

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[1] A prescription drug is a drug which "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug" (21 U.S.C. 353(b)(1)(B)), or which "is limited by an approved application under [21 U.S.C.] 355 * * * to use under the professional supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. 353(b)(1)(C).

[2] On April 22, 1988, the Prescription Drug Marketing Act of 1987, Pub. L. No. 199-293, 102 Stat. 95, became law and amended the FDCA in various respects. Section 333(a) and (b), however, were only redesignated as 21 U.S.C. 333(a)(1) and (2), respectively. § 7(b), 102 Stat. 99. Moreover, none of the provisions of the new Act became effective until July 21, 1988. § 8, 102 Stat. 100-101. Accordingly, all references to the FDCA in this brief are to the Act as codified prior to the adoption of the Prescription Drug Marketing Act of 1987.

them for such use, and they may be dispensed only on the prescription of a licensed physician. *Ibid.* Petitioner, however, distributed those drugs on the black market. In the spring of 1984, he obtained a wholesale drug distribution license from Florida state by misrepresenting that he was an established drug wholesaler in Alabama and would operate his business in that state. In fact, petitioner operated extensively in Florida, and he used various techniques (such as false names and mail drops) to avoid detection by federal and state officials. *Id.* at 5a.

In May 1986, a grand jury in the United States District Court for the Southern District of Florida returned an indictment against petitioner charging him with introducing into interstate commerce specified misbranded human prescription drugs with the intent to defraud and mislead. Before trial, petitioner moved to dismiss the indictment on the ground that it failed sufficiently to specify the charged offenses. The district court denied the motion. Thereafter, petitioner moved to bar the government from presenting evidence that petitioner had acted with the intent to defraud or mislead, within the meaning of 21 U.S.C. 333(b), by distributing the steroids in a manner that would avoid detection by the FDA or Florida regulatory agencies. Petitioner argued that Section 333(b) made it a crime only to defraud or mislead the ultimate consumer. The district court denied the motion on the ground that Section 333(b) does not require the government to prove that a particular individual has been defrauded or misled. 4 R. 91. At trial, the court instructed the jury that it could convict petitioner if he distributed the drugs with the intent to defraud or mislead the federal government or a state regulatory agency as well as "natural persons." Pet. App. 7a.[3] Petitioner was convicted on those counts in the indictment.

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[3] The court instructed the jury that "[i]f you conclude from the evidence as a whole that there was an intent to defraud or mislead any

3. On appeal, petitioner argued that Section 333(b) should be limited to defrauding or misleading consumers, rather than governmental regulatory agencies. The court of appeals rejected that claim, ruling that "the structure of the statutory scheme, the purpose of the statute, and the case law persuade us that Congress meant to encompass conduct intended to defraud government enforcement agencies." Pet. App. 10a.[4] Petitioner also renewed his claim that the indictment failed to identify the offenses charged against him with sufficient particularity. The court of appeals rejected that claim without discussion. *Id.* at 16a.

ARGUMENT

1. Petitioner contends (Pet. 10-15) that the court of appeals misread the FDCA by permitting him to be convicted of a felony violation of the Act for defrauding or misleading a governmental regulatory agency, rather than a consumer. The court of appeals' decision, however, is consistent with the text and fundamental purposes of the Act.

Section 333(a) of Title 21 makes it a misdemeanor to violate any provision of 21 U.S.C. 331, while Section 333(b) makes it a felony for any person to violate Section 331 "with the intent to defraud or mislead." Petitioner

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one of the entities, that is, the natural persons, State Agency, or Federal Government Agency, . . . then you may consider that the necessary intent has been proved." Pet. App. 7a.

[4] The court of appeals also noted that the evidence established petitioner's knowledge that his immediate customers "bought for the purpose of resale" and that there was "sufficient evidence for the jury to find that [petitioner] intended to defraud those unknown third persons to whom [petitioner's customers] would resell the drugs." Pet. App. 8a-9a.

concedes (Pet. 6) that he ran a black market steroid business in a way that both violated Section 331 and was calculated to avoid detection by federal and state regulatory authorities.[5] That is sufficient under Section 333(b), which does not require the government to prove that particular consumers were injured by the scheme.[6] Defrauding or misleading a federal or state regulatory agency also violates that section by preventing the government from carrying out a lawful regulatory function. Cf. *Hammerschmidt* v. *United States*, 265 U.S. 182, 188 (1924) ("To conspire to defraud the United States means primarily to cheat the government out of property or money, but it also means to interfere with or obstruct one of its lawful governmental functions by deceit, craft or trickery, or at least by means that are dishonest."). Moreover, treating petitioner's deception as a felony violation is consistent with the FDCA's underlying purpose. The Act established a comprehensive regulatory scheme governing the interstate distribution of drugs in order to enable the FDA to protect "the lives and health of people which, in the circumstances of modern industrialism, are

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[5] As the court of appeals explained, "[d]uring this period, [petitioner] took various actions to avoid detection. He moved from state to state frequently. He used mail drops rather than his home address when mailing drugs to customers. He repeatedly used false names. He mislabeled his packages as vitamins and 'Herbalife products'. He hired surrogates to pick up and deliver the packages to carriers. He discussed methods of avoiding detection with his customers. * * * In an attempt to obtain a Florida drug wholesaler's permit in the spring of 1984, [petitioner] made affirmative misrepresentations to Florida state drug authorities." Pet. App. 5a.

[6] In fact, the court of appeals found that the evidence was sufficient to establish that petitioner intended to defraud the ultimate consumers of the steroids (Pet. App. 8a-9a), and petitioner does not challenge that finding in this Court.

largely beyond self-protection." *United States* v. *Dotterweich*, 320 U.S. 277, 280 (1943). Deceiving the FDA therefore harms the public by defeating the agency's ability to prevent the unlawful distribution of misbranded drugs.

That construction of Section 333(b) is also consistent with the Act as a whole. As the court of appeals explained (Pet. App. 10a-11a), several subsections of Section 331 prohibit various actions that immediately affect only the government, such as subsection (p), which prohibits failing to register with the FDA or supplying it with certain information. Petitioner's reading of the FDCA would render the felony provision of the Act wholly inapplicable to such conduct, even though Congress clearly intended to make a violation of subsection (p) undertaken with intent to defraud or mislead a felony under Section 333(b). Petitioner's construction of the Act is therefore inconsistent with the "well-settled rule of statutory construction that all parts of a statute, if at all possible, are to be given effect" (*Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 633 (1973)), and with the Court's admonition in cases interpreting the misdemeanor section of the FDCA (21 U.S.C. 333(a)), that its enforcement provisions should be liberally construed in order to effectuate its remedial purposes. *United States* v. *Dotterweich*, 320 U.S. at 284; *United States* v. *Sullivan*, 332 U.S. 689, 692-693 (1948). Finally, petitioner has cited nothing in the legislative history of the Act that stands as "the most extraordinary showing of contrary [congressional] intentions" necessary to deprive the text of the FDCA of its plain meaning. *Garcia* v. *United States*, 469 U.S. 70, 75 (1984).

Petitioner errs in asserting (Pet. 12-14) that the decision below conflicts with the decisions of several other courts of appeals.[7] Most of the cases cited by petitioner do not

[7] Petitioner also errs in claiming (Pet. 14) that the decision below conflicts with *United States* v. *Dotterweich*, 320 U.S. 277 (1943),

refer to this question at all.[8] Moreover, several other courts of appeals have upheld convictions under analogous statutes in similar circumstances. See *United States* v. *Cattle King Packing Co.*, 793 F.2d 232, 237-238 (10th Cir.), cert. denied, 479 U.S. 985 (1986) (upholding convictions for violations of the Federal Meat Inspection Act, 21 U.S.C. (& Supp. IV) 601-624, 661-680,[9] where the defendants sought to avoid the inspection of spoiled meat by federal inspectors); *Bachrack* v. *United States*, 75 F.2d 824, 824-825 (5th Cir. 1935) (stating that 18 U.S.C. 472, which prohibits possession of counterfeit internal revenue stamps, "uses the comprehensive term 'with intent to defraud' for the very purpose of making it immaterial whether the offender intended to defraud the government or some particular individual"); Pet. App. 13a-14a (collecting cases). To our knowledge, the only other decision that has referred to this issue is *United States* v. *Haga*, 821 F.2d 1036 (5th Cir. 1987). Although the court criticized the government's theory that defrauding a government agency rather than a consumer could violate 21 U.S.C. 333(b), that discussion was dicta, as the court itself recog-

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United States v. *Sullivan*, 332 U.S. 689 (1948), and *Kordel* v. *United States*, 335 U.S. 345 (1948). None of those cases addressed this question.

[8] The decisions in *United States* v. *Jamieson-McKames Pharmaceuticals, Inc.*, 651 F.2d 532 (8th Cir. 1981), cert. denied, 455 U.S. 1016 (1982); *United States* v. *Abbott Laboratories*, 505 F.2d 565 (4th Cir. 1974), cert. denied, 420 U.S. 990 (1975); *United States* v. *Barnett*, 587 F.2d 252 (5th Cir.), cert. denied, 441 U.S. 923 (1979); and *United States* v. *Dr. David Roberts Veterinary Co.*, 104 F.2d 785 (7th Cir. 1939), do not mention this issue at all.

[9] The Federal Meat Inspection Act, which is modeled on the FDCA, makes any violation a misdemeanor and provides for enhanced felony punishment "if such violation involves intent to defraud." 21 U.S.C. 676(a).

nized (821 F.2d at 1044 n.17).[10] The decision below therefore does not conflict with *Haga*.[11]

2. Petitioner's fact-bound challenge to the sufficiency of the indictment also does not warrant further review. An indictment is sufficient if it contains the elements of the charged offense, fairly informs the accused of the charge against which he must defend, and enables him to plead an acquittal or conviction as a bar to a future prosecution for the same offense. *United States* v. *Bailey*, 444 U.S. 394, 414 (1980); *Hamling* v. *United States*, 418 U.S. 87, 117

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[10] *Haga* reversed the defendant's conviction due to a variance between the charges in the indictment and the government's proof at trial. He was charged with conspiring to commit an offense against the United States, but was convicted of conspiring to defraud the United States. 821 F.2d at 1045-1046. Although the court criticized (*id.* at 1044-1045 n.17) the government's theory, that issue was not briefed in that case. That criticism, moreover, appears to be based on a misunderstanding of the government's theory. The court believed that, under the government's theory, "only inadvertent (or publicly announced) violations of section 331 would be misdemeanors, because all conscious (and not publicly confessed) violations would necessarily involve a deliberate evasion of established regulatory systems." 821 F.2d at 1044-1045 n.17. However, the government has never argued that any willful violation of Section 331 is a felony; only those violations designed to defraud or mislead would be felonies. In August 1987 we filed a motion asking the court in *Haga* to modify its opinion. Our motion is still pending.

[11] Presently before Congress is H.R. 5210, the Omnibus Drug Initiative Bill, 100th Cong., 2d Sess. (1988). A provision of that bill (§ 10019) would make it a crime, punishable by up to three years' imprisonment and a fine, to distribute or possess with the intent to distribute any anabolic steroid other than for the treatment of disease pursuant to a physician's order. 131 Cong. Rec. H7906, H7908 (daily ed. Sept. 22, 1988). The bill was passed by the House and is currently before the Senate. We will, of course, advise the Court if that bill becomes law.

(1974). The indictment here is sufficient under that standard. It virtually tracks the text of the Act, and it expressly sets forth in each count the drug that was misbranded, the manner in which it was misbranded, the date of its introduction into interstate commerce, and its intended recipient. Additional specificity is not required. See *Hamling* v. *United States*, 418 U.S. at 117-118 (citation omitted) (" 'Undoubtedly the language of the statute may be used in the general description of an offence, but it must be accompanied with such a statement of the facts and circumstances as will inform the accused of the specific offence, coming under the general description, with which he is charged.' ").

Petitioner objects (Pet. 15-21) that the indictment did not identify the party whom he intended to defraud or mislead when he distributed the misbranded drugs into interstate commerce. As explained above, however, Section 333(b) requires only that petitioner have acted with the intent to defraud when he distributed the steroids; it does not demand that the government prove that an identifiable victim of petitioner's scheme was injured. Indeed, petitioner concedes (Pet. 18) that the indictment contained the essential elements of the charge of violating 21 U.S.C. 331(b). That is sufficient, because it is well settled that an indictment need not "allege in detail the factual proof that will be relied upon to support the charges." *United States* v. *Crippen*, 579 F.2d 340, 342 (5th Cir. 1978). Accord, *e.g.*, *United States* v. *Lavergne*, 805 F.2d 517, 521 (5th Cir. 1986); *United States* v. *Castor*, 558 F.2d 379, 385 (7th Cir. 1977), cert. denied, 434 U.S. 1010 (1978); *United States* v. *Bernstein*, 533 F.2d 775, 786-787 (2d Cir.), cert. denied, 429 U.S. 998 (1976).[12]

[12] This case is similar to *Barbee* v. *United States*, 392 F.2d 532 (5th Cir.), cert. denied, 391 U.S. 935 (1968). There, the defendant was charged with the possession of counterfeit currency with the intent to

In any event, petitioner was fully aware of the parties whom the government alleged that he intended to mislead. Almost three months before the start of trial, the government stated in a memorandum in opposition to petitioner's motion to dismiss the indictment that "the user or customer, the Florida Board of Pharmacy, and the Food and Drug Administration were all intentionally defrauded and misled by defendant Bradshaw." 1 R. Doc. No. 37, at 10 n.4. The fact that petitioner was aware of the government's position is confirmed by his motion in limine, in which he sought to prevent the government from presenting evidence that he sought to defraud or mislead federal and state authorities. See Pet. App. 7a. Because petitioner was fully aware of the government's theory of the case, further review of his claim is not warranted.[13]

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defraud, in violation of 18 U.S.C. 472. The defendant argued that the indictment was insufficient because it failed to identify the victim of his counterfeiting scheme. The court held that it was unnecessary for the indictment to contain such an allegation because the act did not require the government to prove that a particular victim had been defrauded. 392 F.2d at 539.

[13] The specificity of the indictment is also sufficient to enable petitioner to plead his conviction in this case as a bar to any future prosecutions for the same offenses. See *Russell* v. *United States*, 369 U.S. 749, 764 (1962) (in a prosecution for refusing to testify before Congress, "[s]ince the indictments set out not only the times and places of the hearings at which the petitioners refused to testify, but also specified the precise questions which they then and there refused to answer, it can hardly be doubted that the petitioners would be fully protected from again being put in jeopardy for the same offense"). Petitioner may also rely on the record developed in this case if necessary to assert a double jeopardy claim. 1 C. Wright, *Federal Practice and Procedure*, § 125, at 365 (2d ed. 1982) ("It has long been the rule that the entire record of the proceedings, and not the indictment or information alone, may be referred to if there is a claim that a subsequent prosecution constitutes double jeopardy," citing, *e.g.*, *Russell* v. *United States*, 369 U.S. at 764; *Bartell* v. *United States*, 227 U.S. 427, 433 (1913)).

CONCLUSION

The petition for a writ of certiorari should be denied.
Respectfully submitted.

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